

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

)
) MDL No. 1456
)
)
)
) Judge Patti B. Saris

THIS DOCUMENT RELATES TO
01-CV-12257-PBS and 01-CV-339

TRIAL OF CLASS 2 AND 3 CLAIMS

**ASTRAZENECA PHARMACEUTICALS LP'S OPPOSITION TO PLAINTIFFS'
MOTION TO STRIKE OR AMEND PARAGRAPH 73 OF ASTRAZENECA'S
PROPOSED FINDINGS OF FACT**

Plaintiffs have moved to strike or amend Paragraph 73 of AstraZeneca Pharmaceuticals LP ("AstraZeneca")'s Proposed Findings of Fact regarding reimbursements for Zoladex made by Class 2 Representative Sheet Metal Workers ("SMW"). Plaintiffs' motion should be denied.

Paragraph 73 of AstraZeneca's Proposed Findings of Fact states:

There were only two Zoladex claims paid by Class 2 Plaintiff Sheet Metal Workers ("SMW") during the class period and one of the two Zoladex claims was not based on the Zoladex AWP. The physician's billed charge was lower than 95% of the Zoladex AWP, so CMS allowed the lower billed charge and not 95% of AWP. SMW made these Medi-gap payments in accordance with the amounts determined by CMS; it did not independently base its payments on the Zoladex AWP.

Plaintiffs dispute two statements in this paragraph. First, Plaintiffs assert that there were more than two Zoladex Medi-gap claims paid by SMW during the class period. Second, Plaintiffs argue that there is no evidence in the record supporting the statement that certain of SMW's

Medi-gap payments for Zoladex were not based on the Zoladex AWP.¹ Although Plaintiffs appear to be correct that SMW paid five claims for Zoladex instead of two, these additional claims only reinforce the factual conclusion set forth in Paragraph 73 that SMW made Medi-gap payments for Zoladex that were not based on AWP.

The two claims referenced in Paragraph 73 of AstraZeneca's Proposed Findings of Fact are the only two Zoladex claims that Plaintiffs have ever identified. See Trial Affidavit of Glenn Randle at ¶ 6 (citing SMWMASS 001174-76) (filed Oct. 27, 2006); Bates Numbers Used in Sheet Metal Workers Claims Coverage Analysis (listing SMWMASS 001289-90) (attached hereto as Exhibit A). Plaintiffs did not offer any other evidence of Zoladex claims paid by SMW at trial. Instead, Plaintiffs appear to assume that all SMW claims forms are in evidence just because Exhibit 4012, a summary chart based on the SMW claims forms, was admitted. See Pl. Mot. Strike at 1. Plaintiffs are wrong as a matter of law. See FED. R. EVID. 1006 (2006); see also Stephen A. Saltzburg, et al., Federal Rules of Evidence Manual Section 1006, (2006); ("before offering a summary under Rule 1006, the proponent will have to lay a proper foundation for the admission of the original"); see also United States v. Milkiewicz, 470 F.3d 390, 396-98 (1st Cir. 2006) (explaining that the court may choose to affirmatively admit underlying documents into evidence, but summaries "typically are substitutes in evidence for the voluminous originals").

Exhibit 4012 merely demonstrates the existence of a single Zoladex claim in two separate years. See Pl. Mot. Strike at 1. Exhibit 4012 does not otherwise quantify, or provide any information about, specific Zoladex Medi-gap claims allegedly paid by SMW in any year.

¹ Although Plaintiffs state in their motion that AstraZeneca failed to send a letter to Plaintiffs disputing whether SMW's payments were based on AWP, Plaintiffs have since conceded that they did, in fact, receive such a letter but overlooked it.

Plaintiffs were required to separately establish the admissibility of the underlying forms and offer them into evidence, but they failed to do so. See Stephen A. Saltzburg, et al., Federal Rules of Evidence Manual Section 1006, (2006).

Nonetheless, AstraZeneca would have no objection to a motion by Plaintiffs to admit into evidence the Zoladex claims forms produced by SMW that were paid during the class period. Those forms and related documents, attached hereto as Exhibit B, indicate that SMW paid five Zoladex claims during the class period.² If these claims forms and related documents are admitted into evidence, AstraZeneca will agree to amend Paragraph 73 accordingly to reflect that five Zoladex claims were paid by SMW instead of two.

With the exception of the number of claims at issue, however, the rest of Paragraph 73 is accurate; three of the five Zoladex claims paid by SMW during the class period were not based on AWP. See Exhibit B at SMWMASS 001174-76, SMWMASS 001339-41, SMWMASS 001432-34. These three claims were all submitted by the same physician practice – Pioneer Valley Urology in Springfield, Massachusetts. In the years these claims were paid, the allowed amount for Zoladex under Medicare Part B was the lower of 95% of the Zoladex AWP or the physicians actual charge. See 142 C.F.R. § 405.517. The claims forms indicate that Pioneer Valley Urology charged \$1275.00 for three units of J9202, which is the J-code for Zoladex. See Exhibit B at SMWMASS 001175, SMWMASS 001340, SMWMASS 001433. In the years these claims were paid, however, 95% of the AWP for the three-month dosage of Zoladex (referred to as three units on the claim forms) was \$1339.47.

² The five claims included in Exhibit B are identified as: SMWMASS 001086-87 (paid in 2001); SMWMASS 001174-76 (paid in 2001); SMWMASS 001288-90 (paid in 2001); SMWMASS 001339-41 (paid in 2002); and SMWMASS 001432-34 (paid in 2003). The 2004 claims included in the SMW production are no longer encompassed within the class period, so they are not relevant to this analysis and are not included in Exhibit B. See the Court's Order of 11/02/06, Docket No. 3299, at 24 (excluding reimbursements made in 2004 from Class 2).

Because the amount actually charged by the physician was less than 95% of the AWP for the three month dosage of Zoladex, the Medicare “allowed amount” for J9202 was the physician’s lower billed charge of \$1275.00, not 95% of the Zoladex AWP (which would have been \$1339.47). See Exhibit B at SMWMASS 001176, SMWMASS 001341, SMWMASS 001434. Accordingly, the co-insurance paid by SMW was 20% of the billed charge, or \$255.00, not 20% of 95% of the Zoladex AWP – which would have been \$267.89. Id. Indeed, SMW witnesses testified that SMW simply pays 20% of the Medicare allowable; they do not independently calculate their Medi-gap payments based on AWP. See Revised Trial Affidavit of Glenn Randle, ¶¶ 4-5; 11/07/06 Tr. 9:9-11:3 (Testimony of S. Faulkner).³ Accordingly, since the Medicare allowable for this claim was not based on the Zoladex AWP, SMW’s Medi-gap co-payment was not based on the Zoladex AWP.⁴

In sum, with the exception of the number of claims at issue, Paragraph 73 is accurate. Indeed, the additional claims identified by Plaintiffs only emphasize the fundamental problem with the Class 2 claims – the amount paid by SMW is determined by CMS and not by any action of AstraZeneca. Similarly, Plaintiffs’ request for aggregate damages is without merit, because it is based on manufacturer data regarding units of Zoladex sold, not Plaintiff data regarding units actually reimbursed on the basis of AWP.

³ Plaintiffs’ assertion that AstraZeneca failed to introduce any evidence at trial regarding the basis for SMW’s reimbursements is backwards. It is *Plaintiffs’* burden to prove that SMW reimbursements were based on AWP; it is not AstraZeneca’s burden to prove that SMW reimbursements were not based on AWP. Moreover, AstraZeneca’s proposed finding of fact that certain Zoladex claims were not based on AWP is supported by the documents themselves, the statute, and simple math.

⁴ AstraZeneca does not dispute that the other two claims included in Exhibit B were paid based on AWP. See SMWMASS 001086-87; SMWMASS 001288-90. Both of those claims were submitted by Urology Group of Western New England, which charged \$1350.00 for a three-month dosage of Zoladex – an amount greater than 95% of the Zoladex AWP. See SMWMASS 001086, SMWMASS 001289. As a result, Medicare allowed 95% of the Zoladex AWP, or \$1339.47. See SMWMASS 001087, SMWMASS 001290. The co-insurance calculated by CMS and paid by SMW was therefore based on the Zoladex AWP.

Accordingly, for the reasons stated above, AstraZeneca will consent to a motion by Plaintiffs to admit the SMW claims forms attached hereto as Exhibit B. Should the Court grant that request, AstraZeneca will voluntarily amend the first sentence of Paragraph 73 to reflect that five Zoladex claims were paid by Class 2 Plaintiff Sheet Metal Workers (“SMW”) during the class period (and that three of the five were not paid based on AWP). In all other respects, AstraZeneca respectfully requests that the Court deny Plaintiffs’ motion to strike or amend Paragraph 73.

Dated: February 5, 2007

Respectfully submitted,

By: /s/ Katherine B. Schmeckpeper

Nicholas C. Theodorou (BBO # 496730)
Katherine B. Schmeckpeper (BBO #663200)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02210

D. Scott Wise
Michael S. Flynn
Kimberley D. Harris
Davis Polk & Wardwell
450 Lexington Avenue
New York, NY 10017

Attorneys for AstraZeneca Pharmaceuticals LP

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered on February 5, 2007 to counsel for plaintiffs and to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, via LexisNexis File & Serve.

By: /s/ Catherine N. Karuga
Catherine N. Karuga